

## INFORMATION PAPER

Military Vaccine Agency  
5 April 2013

SUBJECT: Vaccinia Immune Globulin Intravenous (Human) (VIGIV)

1. Purpose. Define procedures for acquiring IV-VIG

2. Facts.

a. The DoD requires smallpox vaccination of designated at-risk military personnel, DoD civilian personnel classified as emergency-essential per DoD Directive 1404.10, and members of smallpox response teams (e.g., smallpox epidemic response teams, treatment teams, and public health teams). A small number of people may be at increased risk for side effects after receipt of the smallpox vaccine. VIGIV is indicated for the treatment or modification of certain adverse conditions induced by the smallpox vaccine.

b. The Director of the Military Vaccine (MILVAX) Agency will act as final releasing authority for all Food and Drug Administration (FDA) licensed and DoD owned VIGIV.

c. MILVAX is responsible for FDA required post-licensure safety surveillance activities for VIGIV in coordination with the manufacturer.

c. Under routine circumstances, the need for VIGIV will be validated by a board-certified infectious disease (ID) or allergy-immunology (AI) specialist before administration. The Vaccine Healthcare Centers Network (VHCN) and MILVAX will provide and coordinate professional consultation services to optimize clinical use of IV-VIG.

3. Procedures

a. Clinician identifies a vaccinee with adverse reaction that may benefit from treatment with VIGIV.. This would include but is not limited to: aberrant infections induced by vaccinia virus that include accidental implantation in eyes, mouth, or other areas where vaccinia infection would constitute a special hazard; eczema vaccinatum; progressive vaccinia; severe generalized vaccinia; or vaccinia infections in people who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in people who have eczematous skin lesions because of either the activity or extensiveness of such lesions. VIGIV is not indicated for isolated vaccinia keratitis or postvaccinial encephalitis.

b. Clinician will consult with a local ID or AI physician if possible. Clinician will then begin the consultation process with the VHCN by calling the DoD Vaccine Clinical Call Center at 866-210-6469. VHCN or attending physician will notify the Military Vaccine (MILVAX) Agency with case specifics. The ID or AI specialist, in consultation with the VHCN and MILVAX will request the release of IV-VIG.

c. Deputy Director, MILVAX (703-681-5699/571-278-2767 or DoD Clinical Call Center 24/7 at 866-210-6469), email [Jorge.d.carrillo.mil@mail.mil](mailto:Jorge.d.carrillo.mil@mail.mil) will coordinate the release and shipment of CONUS and OCONUS VIGIV with the United States Army Medical Materiel Agency Distribution Operations Center (USAMMA-DOC). VIGIV is prepositioned at USAMMA, Fort Detrick, MD, as well as Hawaii (Tripler Army Medical Center), Okinawa, Japan (Camp Foster), Republic of South Korea (Brian Allgood Army Community Hospital), and Germany (USAMMCE).

d. The attending clinician must read the package inserts and case-report form while considering the patient's clinical situation. The clinician then obtains needed specialty consults and administers VIGIV if warranted. Clinician draws serum specimens before infusion and 5 days after each VIGIV dose. Freeze serum vials at -20°C until ready to ship. Obtain patient's consent to release serum samples. Ship serum vials at -20°C and case-report form to CDC in accordance with detailed instructions in the serum processing kit that accompanies VIGIV. Send copy of case-report form to VHCN.

#### 4. References.

a. Advisory Committee on Immunization Practices. Smallpox Vaccinations and Adverse Reactions, MMWR 2003;52(RR04): 1-28:  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm>

b. CDC VIG information website:  
<http://www.bt.cdc.gov/agent/smallpox/vaccination/vig.asp>

c. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by Military Vaccine Agency: [www.vaccines.mil/smallpox](http://www.vaccines.mil/smallpox)

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